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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,928	02/04/2004	Jerry A. Douglas	N9914	3499

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EXAMINER	
BARHAM, BETHANY P	
ART UNIT	**PAPER NUMBER**
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,928	DOUGLAS, JERRY A.	
	Examiner	Art Unit	
	Bethany P. Barham	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicant's Response and Claim Amendments filed on 06/27/2007 are acknowledged. Claims 1-18 and 21-26 are pending. Claims 1-18 and 21-26 are rejected.

MAINTAINED REJECTIONS

Double Patenting

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 4 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3, 5 and 8 of copending Application No. 11/238,449. This is

a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 and 19-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-13, and 16-19 of US 5,174,990, 1, 8-12, and 15-17 of US 5,310,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in subject matter pertaining to a composition comprising disodium EDTA in overlapping ranges, hydrogen peroxide (an oxidant) in overlapping ranges, zinc chloride in overlapping ranges, sodium citrate, sodium lauryl sulfate, and glycerin in amounts as claimed in the instant application, the pH of the compositions is overlapping and the

method of preparation disclosed is similar in its steps. All compositions are drawn to use on skin, tissue or mouth areas to treat inflammation.

Claims 1-6, 12, 15-18, 21, 23 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 5-18 of copending application 11/238, 449. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in subject matter pertaining to a composition and a method of treating inflammatory response comprising a composition of precursor salts and at least one precursor oxidant mixed stepwise to produce a solution with zinc, sodium, citrate, and chloride ions, sodium lauryl sulphate, menthol, EDTA, glycerin, etc for treating at least once daily, three to five times per day with a pH of 3.5-4.5, applying the composition to an area that has dermatological inflammatory response, and applying to skin or tissue area.

RESPONSE TO ARGUMENTS

Applicant's arguments with respect to claims 1-18 and 21-26 have been considered but not persuasive. Applicants argue that the claim 4 is not statutory over the claims 3, 5, and 8 in application 11/238,449, the examiner respectfully disagrees as both compositions inflammatory response comprise:

"from about 0.02% to about 0.08% disodium EDTA;

from about 0.04% to about 0.20% sodium lauryl sulfate;

from about 0.015% to about 0.20% sodium citrate;

and from about 0.01% to about 0.019% zinc chloride,

and wherein the at least one precursor oxidant further includes:

from about 0.5% to about 3% oxidant

and

further comprising from about 3.6% to about 4.0% glycerin."

Also, Applicants arguments with respect to the obviousness-type double patenting rejections over patents US 5,174,990 and US 5,310,546; and co-pending application 11/238,449 are not persuasive. The patents and application teach the same composition and the same method of preparation for the composition and substantially the same method of treating inflammation to the skin, tissue, mouth, gums, etc and as such the double patenting rejections of record stand.

NEW REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 22, 24 and 26 contain the trademark/trade name Pluronic F-127. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used

properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe poloxamer 407 (generic name) and, accordingly, the identification/description is indefinite.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 14-15, 21-22 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,104,644 ('644).

The limitations of claims 1-6 are taught by '644:

- '644 is a mouthrinse preparation contains about 0.5 to about 3 % hydrogen peroxide, zinc chloride, sodium lauryl sulfate, and sodium citrate in amounts sufficient to provide antiplaque, antibacterial, astringent, and anticoagulant properties (abstract). '644 also teaches including disodium EDTA, glycerin, and citric acid (col. 9, lines 36-45). The compositions of '644 are taught to produce a

final desired pH of about 3.5 to about 4.0, or other variants have pHs of about 3.5-5.5 and 6-7 (col. 9, line 5-13).

- '644 teaches in Example 1 a mouth rinse comprising (all in % by weight) 0.03-0.05 disodium EDTA, 0.04-0.08 sodium lauryl sulfate, 0.03-0.06 sodium citrate, 0.02-0.04 zinc chloride and 0.05-3 hydrogen peroxide (a 3% soln as shown in the 1st table). Example 1 also teaches glycerin 2.5-3.5% and citric acid 0.01-0.05% by weight and a pH of 3.5-4.0 (as shown in the 2nd table).

The limitations of claims 7-11, and 14-15 are taught by '644:

- Claims 1-6 of '644 teach the limitations of the instant claims 7, 9-10, 14 and 20 except for the EDTA, which is shown in all the examples of '644 and is found overlapping with the instant applications' range in Example 1 as shown above, as are all the ingredients claimed shown in overlapping ranges with the instant application in example 1. Further, '644 teaches citric acid and pH of instant claims 8 and 11 in example 1 as shown above.
- The composition of '644 it taught to control etiological factors, microbiota, local factors, plaque and inflammation, and to kill bacteria, restore the edematous tissue to the normal state, check inflammatory processes responsible for gingivitis and heal hemorrhagic tissue (col. 1, 9-25). Also, '644 is taught to contain components that are known astringents and anti-inflammatory agents (col. 6, lines 59-65) and that using a rinse in oral irrigation that has heavy concentration of oxygen, antimicrobial agents, anti-inflammatory agents and anti-surface tensions agents will impede the growth process of disease causing

microbiota and furnish oxygen for the growth of normal flora of the oral cavity, helping the tissues of the oral cavity maintain a normal host-parasite balance (col.3, line 67-col. 4, line 6).

The limitations of claims 21-26 are taught by '644:

- Examples 1 and 2 as taught above also teach including poloxamer 407 (which is generic for Pluronic F-127), flavorants such as peppermint oil and menthol, and ethanol as specifically identified by SD alcohol 38.

Claims 1-6 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,086,856 ('856).

The limitations of claims 1-6 and 21-22 are taught by '856:

- '856 teach oral hygiene formulations comprising foaming surfactants as mouthwashes, rinses and dentifrices containing one or more antimicrobial, anti-plaque, and anti-cariogenic agents (abstract)
- Example 5 teaches a hydrogen peroxide based aqueous mouthwash comprising 0.6% H_2O_2, 0.02% zinc chloride, 0.03% sodium citrate, 0.02% citric acid and 0.2% sodium lauryl sulfate all in weight percent as described in example 2 of US 5,174,990 using the method of Example 1 of the patent and the ingredients and their concentrations are substantially as given is col. 6 of the patent except sodium lauryl sulfate, which is recited above (col. 11, lines 33-45). The ingredients further include glycerin at 2.822%, also SDA38B2, Poloxamer 407 and teach that it is 0.016% zinc chloride that is used.

Claims 1-5, 7-11, 14-15, 21-22 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,174,990 ('990) or US 5,310,546.

The limitations of claims 1-5 are taught by '990 or '546:

- '990 or '546 is a mouthrinse preparation containing between about 0.25 and about 0.65 % hydrogen peroxide, about 0.1% zinc chloride, at least about 0.0012% sodium citrate and at least about 0.03% sodium lauryl sulfate, and at least about 0.006% citric acid (abstract, claim 1). '990 also teaches glycerin in the amount of about 1.8- about 9% (col. 4, lines 20-21, claims 9-10), disodium EDTA from about 0.022 to 0.1% (col. 4, lines 24-26, claims 12-13) and a pH from about 3.5 to about 4.5 (col. 3, lines 45-48). Further, '990 or '546 claims 16 and 17 claim ingredients within the instant applications' ranges.
- Specifically, '990 or '546 Example 2 teaches a mouthrinse comprising 0.595% H_2O_2, 0.016% zinc chloride, 0.024% sodium citrate, 0.0158% citric acid, 0.044% disodium EDTA, and 0.06% sodium lauryl sulfate all in weight percent, with a pH of 3.925.

The limitations of claims 7-11, and 14-15 are taught by '990 or '546:

- '990 or '546 teach disodium EDTA from about 0.022 to 0.1% (col. 4, lines 24-26, claims 12-13) and between about 0.25 and about 0.65 % hydrogen peroxide (col. 3, lines 2-3), about 0.005 and about 0.1% zinc chloride (col. 3, lines 15-17), at least about 0.0012% and up to about 0.2% or greater sodium citrate (col. 3, lines 47-48) and at least about 0.03% sodium lauryl sulfate, in ratio with zinc chloride

in the range of from about 2 to 1 to about 8 to 1 (col. 3, lines 35-40), and always greater than about 0.005% citric acid to maintain the pH of about 3.5 to about 4.5 (col. 3, lines 53-59).

- Example 3 of '990 or '546 teaches that the composition of the invention is capable of reducing inflammation in patients 100% of the time when administered to their mouths. Example 4 of '990 or '546 shows that the composition kills bacteria and/or inhibits their growth.

The limitations of claims 21-22 and 25-26 are taught by '990 or '546:

- Examples 2 of '990 and '546 teaches including SDA38B2 and poloxamer 407. Further, claimed in '990 claims 6-8 and '546 claims 5-7 are flavorants such as peppermint oil, menthol and a solubilizer such as poloxamer 407.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,104,644 in view of US 6,086,856.

The limitations of claims 15-18 and 25-26 are taught by '644 in view of '856:

- '644 is taught above.
- '644 does not teach a method of applying at least once a day and 3 to 5 times daily of applying to an inflamed surface.
- '856 teaches in Example 8 that the system is well suited for the delivery of non-ingestible expectoratable formulations to the oral cavity as medicaments, used for cleansing minor wound or irritations of the mouth or gums, for example, a small amount of the medicated e.g. H_2O_2 containing foam is dispensed and applied to the affected area, and that the foam can be used up to 4 times daily (after meals and at bedtime) (col. 12, lines 18-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of '644 and '856 since both teach H_2O_2 based mouthwash systems for treating irritation and inflammation. One of ordinary skill in the art would have been motivated to combine since the ranges set forth in example 1 and the claims of '644 encompass the example 5 of the '856. Thus one seeking how often to use the medicament would look to '856, which discloses a proper method of use.

Claims 12-13 and 23-24 are rejected under 35 U.S.C. 103(a) as being anticipated by US 5,174,990 ('990) or US 5,310,546 ('546).

The limitations of claims 12-13 and 23-24 are taught by '990 or '546:

- '990 or '546 Example 1 teaches a zinc chloride solution is prepared by adding zinc chloride to deionized water and allowing the heat to dissipate from the solution after mixing.
- Then a remaining ingredient solution is prepared in deionized water of disodium EDTA, sodium citrate, sodium lauryl sulfate, etc, and is mixed with the zinc chloride solution and allowing the heat to dissipate from the solution after mixing.
- The alcohol solution was then mixed in (which contains SD alcohol 38B2, peppermint oil, poloxamer 407)
- Lastly the hydrogen peroxide solution was added to the previous solution and mixed for several minutes to form a stabilized mouthrinse containing hydrogen peroxide (col. 5, lines 30-62, claim 18).
- It is the examiner's opinion that one of ordinary skill in the art (PhD level) at the time the invention was made would know how long to wait in order to allow the heat to dissipate from the solution or the solution to cool after mixing has occurred, or to vary mixing times of the composition.

Response to Arguments

Applicant's arguments with respect to claims 1-18 and 21-26 have been considered but not persuasive and are moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicant argues that the compositions and method of preparation are different simply because their intended use is different,

however the Examiner respectfully points out that the compositions and method of preparation are the same and that intended use is not given any patentable weight. The claimed composition and method of preparation are claimed by the prior art and/or specific examples are taught with the ranges identical or a single point within the instant claimed range for each and every component as detailed extensively by the examiner above (for example refer to '990 examples 1-2 and claims 1, 6-13, 17 and 18). MPEP 2131.03 states that "[W]hen, as by a recitiation of ranges or otherwise, a claim covers several compositions, the claim is anticipated' if one of them is in the prior art." And further the MPEP 2129 states that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference....When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art."

The Applicant further argues that the method of treatment of dermatological inflammatory response is not anticipated and/or obvious over a method of treating inflammatory response in tissue, oral mucosal, mouth, etc as taught by the prior art. However, the Examiner respectfully disagrees and points out that the process of inflammation occurs in the same manner in any tissue and that the various known anti-inflammatory agents, which are used to treat inflammation treat numerous different tissue types. The art taught above teaches that inflammation is reduced in tissue, oral mucosal, mouth, etc in patients given the composition as taught by the prior art and as instant claimed. As such the instant claims remain rejected over the prior art.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany P. Barham whose telephone number is 571-272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B.P. Barham
Examiner 1615

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